

The above amendment is responsive to points set forth in the Official Action. In this regard, the feature of claim 5 has been incorporated into claim 1, and claim 5 has been canceled.

Claim 6 has been made dependent on thus-amended claim 1.

The significance of the foregoing amendments will be apparent from the remarks below.

Claims 1 to 16 are rejected under 35 USC 103 as being unpatentable over Ercoli et al. and Derwent Abstract 93-104198.

This rejection is respectfully traversed.

The present invention relates to a difluprednate emulsion comprising difluprednate, an oil, water and an emulsifier, wherein the oil comprises a fatty acid ester of glycerol. The fatty acid ester of glycerol may be, for example, castor oil, peanut oil, cottonseed oil, soybean oil, olive oil or a medium chain fatty acid triglyceride, and the emulsifier may be, for example, a surfactant (nonionic surfactant).

Derwent Abstract 93-104198 (JP-A-5-43465) discloses, in Examples 1 and 4 and Comparative Example 1, a lotion comprising at least difluprednate, monostearic acid polyoxyethylene (nonionic surfactant), squalane (oil) and purified water, and in Examples 2 and 3, a lotion comprising at least difluprednate, monostearic acid polyoxyethylene (nonionic surfactant), liquid paraffin (oil) and purified water. JP-A-5-43465 teaches, "as the oil phase component, liquid paraffin, white petrolatum, microcrystalline wax, hard paraffin and the like or a mixture thereof can be used in an amount of 2-20% by weight, preferably 2-10% by weight, of the entire composition".

Ercoli et al. (U.S. 3,780,177) discloses, in Example 7, a cream comprising at least difluprednate, sodium lauryl sulfate (surfactant), liquid paraffin (oil) and distilled water, and in Example 8, a cream comprising at least an analog of difluprednate, Tween 80 (nonionic surfactant), liquid paraffin (oil) and distilled water.

The emulsion of the present invention is preferably used in the form of an eye drop, a nasal drop or an ear drop. Therefore, a fatty acid ester of glycerol, which is of low toxicity and irritation, is preferable as the oil. In contrast, the liquid paraffin and squalane disclosed in the two

references mentioned above are not suitable for use in eye drops, nasal drops or ear drops, especially as recited in claims 12 and 16 to 18.

As shown in Experimental Example 1 in the present specification, the emulsion of the present invention is superior in the transfer of difluprednate to a lesion (e.g., intraocular transfer). The above-mentioned two references do not disclose or even suggest the superior transfer of difluprednate to a lesion.

The emulsion of the present invention affords advantageous effects in that it is 1) of low toxicity and irritation and is suitable for use in the form of eye drops, nasal drops and ear drops, and 2) is superior in the transfer of difluprednate to a lesion.

Neither reference suggests that the use of the oil comprising fatty acid ester of glycerol leads to an emulsion showing such advantageous effects. Consequently, the emulsion of the present invention is not obvious from these references.

No further issues remaining, allowance of this application is respectfully requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned at the telephone or facsimile number below.

Respectfully submitted,

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